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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/671,767 | 09/29/2003 | Takashi Kitaoka | 018961-065 | 7544 |

21839 7590 10/24/2005

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| EXAMINER |
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PRONE, CHRISTOPHER D

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| ART UNIT | PAPER NUMBER |
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3738

DATE MAILED: 10/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/671,767

Applicant(s)

KITAOKA ET AL.

Examiner

Christopher D. Prone

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7 and 9-19 is/are rejected.
- 7) ☐ Claim(s) 6, 8 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7, 9, 10-15, and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by European Patent Application Publication Terumo (EP 0 795 304 A1).

In reference to claims 1-4, 7, 9, 10, 12, 14, 15, and 17 Terumo discloses the same invention being an indwelling stent formed in a substantially tubular shape comprising at least 2 annular units (4a-4f) arranged in an axial direction of said stent, each of said annular units comprises at least 4 annular elements referenced as elements (2a-2d) that are not arranged rectilinearly, an opening in a central portion thereof at reference numbers (17a-17e), adjacent portions of said annular elements are joined to each other through a joint (3a-3c), adjacent annular units being interconnected at their joints by at least one link (5a-5e) that is parallel to a axis but not continuous with another adjacent link, and a end portion with roughly semi-elliptic shape, said annular elements in each said annular unit are arranged so that one of each adjacent pair of said annular elements is axially offset in the axial direction of said stent, end portions of each said annular unit are projected zigzag, said zigzag projected end portion of said annular unit is in the state of penetrating into the adjacent annular unit, and said joints in

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each said annular unit are substantially parallel to the stent axis shown in figures 6-12 of Terumo.

Note: In regard to claims 11 and 13, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (MPEP 2113).

In reference to claims 11 and 13, which are product by process claims, the invention of Terumo meets all the structural requirements claimed. Therefore it is inherent that the invention of Terumo is produced with a predetermined outside diameter by use of a plastically deformable material-made pipe and then reduced in diameter by compressing from outside.

In reference to claim 18 Terumo discloses the same invention being an indwelling stent as disclosed above, wherein adjacent portions of said annular elements in each annular unit are joined to each other through a joint and the joints connecting the annular elements are substantially parallel to the stent axis.

In reference to claim 19 Terumo discloses the same invention being an indwelling stent wherein the link connecting first and second adjacent annular units is circumferentially shifted relative to the link connecting second and third adjacent annular units.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 and 16 are rejected under 35 U.S.C. 103 as being unpatentable over Terumo in view of Fischell (USPN 5,695,516).

Terumo discloses the invention substantially as claimed being an indwelling stent as described above. However, Terumo does not disclose a radiopaque marker band.

Fischell teaches the use of a stent comprising a radiopaque material marker described in column 3 on lines 22-29 in the same field of endeavor for the purpose of enhancing the visibility of the stent.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the stent structure of Terumo with radiopaque markers taught by Fischell in order to enhance the stents trackability giving the operator better visualization of the stent during implantation.

Allowable Subject Matter

Claim 6, 8, and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Prone whose telephone number is (571) 272-6085. The examiner can normally be reached on Monday Through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



CDP

Christopher D Prone
Examiner
Art Unit 3738



CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
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